UNITED STATES DISTRICT COURT
FOR THE NORTHISN DISTRICT OF TEXAS
DALLAS DIVISION

GEORGE J. PONIEWAZ
JILL PONIEWAZ
S62 W23187 FERN DRIVE
WAUKESHA, WI 53189,

CIVIL ACTION NO:

JURY TRIAL DEMANDED

Plaintiffs

-against-

DePUY ORTHOPAEDICS, INC, DePUY PRODUCTS, INC.' DEPUY INTERNATIONAL LIMITED, JOHNSON & JOHNSON SERVICES, INC.; and JOHNSON & JOHNSON, INC.,

Defendants

COMPLAINT FOR DAMAGES

NOW COME the Plaintiffs George J. Poniewaz and Jill Poniewaz ("Plaintiffs"), and as and for their complaint against the Defendants DEPUY ORTHOPAEDICS, INC., DEPUY PRODUCTS, INC., DEPUY INTERNATIONAL LIMITED, JOHNSON & JOHNSON SERVICES, INC., and JOHNSON & JOHNSON, INC., allege upon information and belief as follows:

PARTIES

1. Plaintiff George J. Poniewaz is, and at all times relevant to this Complaint was, a resident of the city of Waukesha, in the state of Wisconsin. Plaintiff George J. Poniewaz was born in 1957.

2. Plaintiff's Spouse, Jill Poniewaz, is, and at all times relevant to this Complaint was, a resident of the city of Waukesha, in the state of Wisconsin, and claims damages as a result of loss of consortium.

3. At the time of the Plaintiff's implantation with the Defendants' Pinnacle Acetabular Cup System ("Pinnacle Device") on June 5, 2008, he was a resident of the City of Waukesha, County of Waukesha, State of Wisconsin.

4. Defendant DEPUY ORTHOPAEDICS, INC. is, and at all times relevant to this Complaint was, an Indiana Corporation with its principal place of business at 700 Orthopaedic Drive, Warsaw, Indiana 46581.

5. At all relevant times to this Complaint, DEPUY ORTHOEPAEDICS, INC., designed, manufactured, tested, marketed, distributed and sold the subject metal-on-metal Pinnacle Device implanted in the Plaintiff, either directly or indirectly, to customers throughout the United States, including the Plaintiff, George J. Poniewaz, in the county of Waukesha, state of Wisconsin.

6. Defendant DEPUY PRODUCTS, INC. is, and at all times relevant to this Complaint was, an Indiana Corporation with its principal place of business at 700 Orthopaedic Drive, Warsaw, Indiana 46581.

7. At all relevant times to this Complaint, DEPUY PRODUCTS, INC., designed, manufactured, tested, marketed, distributed and sold the metal-on-metal Pinnacle Device implanted in the Plaintiff, either directly or indirectly, to customers throughout the United States, including the Plaintiff, George J. Poniewaz, in the county of Waukesha, state of Wisconsin.

8. Defendant DEPUY INTERNATIONAL LIMITED is a corporation organized and existing pursuant to the laws of the United Kingdom, with its principal place of business located at St. Anthony's Road, Leeds, West Yorkshire, LS11 8DT, United Kingdom.

9. At all relevant times to this Complaint, DEPUY INTERNATIONAL LIMITED, designed, manufactured, tested, marketed, distributed and sold the metal-on-metal Pinnacle Device, implanted in the Plaintiff, either directly or indirectly, to customers throughout the United States, including the Plaintiff, George J. Poniewaz, in the county of Waukesha, state of Wisconsin.

10. Defendant JOHNSON & JOHNSON SERVICES, INC. is, and at all times relevant to this Complaint was, a New Jersey Corporation with its principal place of business at One Johnson & Johnson Plaza, New Brunswick, New Jersey 08933, and was the parent company of DEPUY ORTHOPAEDICS, INC.

11. At all relevant times to this Complaint, Defendant JOHNSON & JOHNSON SERVICES, INC., as the parent company of DePUY ORTHOPAEDICS, INC., designed, manufactured, tested, advertised, marketed, distributed and sold the metal-on-metal Pinnacle Device, implanted in the Plaintiff, either directly or indirectly, to customers throughout the United States, including the Plaintiff, George J. Poniewaz, in the county of Waukesha, state of Wisconsin.

12. Defendant JOHNSON & JOHNSON, INC. is, and at all times relevant to this Complaint was, a New Jersey Corporation with its principal place of business at One

Johnson & Johnson Plaza, New Brunswick, New Jersey 08933, and was the parent company of DEPUY ORTHOPAEDICS, INC.

13. At all relevant times to this Complaint, Defendant JOHNSON & JOHNSON, INC., as the parent company of DePUY ORTHOPAEDICS, INC., designed, manufactured, tested, advertised, marketed, distributed and sold the metal-on-metal Pinnacle Device, implanted in the Plaintiff, either directly or indirectly, to customers throughout the United States, including the Plaintiff, George J. Poniewaz, in the county of Waukesha, state of Wisconsin.

JURISDICTION AND VENUE

14. This Court has subject matter jurisdiction over the parties pursuant to 28 U.S.C. § 1332(a) because Plaintiffs and Defendants are citizens of different states and the amount in controversy exceeds $75,000.00, exclusive of interest and costs.

15. Venue is proper in this Court based on the Court's Case Management Order #1, filed on June 29, 2011, which permits direct filing into this Court and for consideration for transfer into MDL Docket No. 3:11-MD-2244-K.

16. Venue of this case is appropriate in the Eastern District Court of the State of Wisconsin. Plaintiffs state that but for Case Management Order #1 permitting direct filing into the Northern District of Texas, Plaintiff would have filed in the Eastern District Court of the State of Wisconsin. Therefore, Plaintiffs respectfully request that at the time of transfer of this action back to the trial court for further proceedings that this case be transferred to the above referenced District Court.

FACTUAL ALLEGATIONS

A. Background And Summary Of Action

17. Defendants began manufacturing, marketing, and distributing the Pinnacle Device in 2001. The Pinnacle Device was designed, developed, and sold for human hip joints damaged or diseased due to fracture, osteoarthritis, rheumatoid arthritis, and avascular necrosis. The Pinnacle Device is designed to be fastened to human bone with surgical screws. The Pinnacle Device was designed and sold to provide pain relief and consistent and smooth range of motion. Defendants marketed the Pinnacle Device as having significant advantages over other hip devices and hip replacement systems. Defendants marketed and described the Pinnacle Device as "[u]niquely designed to meet the demands of active patients like you -and help reduce pain." Defendants advertised the Pinnacle Device as a superior device featuring TrueGlide technology, allowing the body to create a thin film of lubrication between surfaces, which enables "a more fluid range of natural motion."

18. Defendants also advertised and sold the Pinnacle Device as the best surgical option that "[r]ecreates the natural ball-and-socket joint of your hip, increasing stability and range of motion."

19. More than 1,300 adverse reports have been submitted to the U.S. Food and Drug Administration (FDA) regarding failures or complications of the Pinnacle Device.

20. Defendants were and are aware that the use of the Pinnacle Device may result in metallosis, biologic toxicity, and a high failure rate. The use of the Pinnacle Device results in unsafe release of toxic metal ions into hip implant recipients' tissue and bloodstream. Defendants are also aware that metal particles from the Pinnacle Device

results in metallosis, tissue death, bone erosion, and development of tumors. Particulate debris from the Pinnacle Device may cause severe inflammation, severe pain, tissue and bone loss, and other related diseases.

21. Defendants are aware that certain Pinnacle Device recipients have elevated cobalt and chromium levels greatly exceeding acceptable safety standards.

B. The Pinnacle Device With An "Ultamet" Liner

22. The Pinnacle Device was developed for the purpose of reconstructing diseased human hip joints from conditions such as osteoarthritis, rheumatoid arthritis, avascular necrosis (AVN), fracture, and other degenerative conditions. The hip joint connects the thigh (femur) bone of a patient's leg to the patient's pelvis. The hip joint consists of a ball and socket. The socket portion of the hip is called the acetabulum. The femoral head at the top of the femur bone rotates within the curved surface of the acetabulum.

23. The Pinnacle Device is made up of four components: the metal femoral stem is inserted inside the femur bone, the metal femoral head (or ball) connects to the top of the stem and then makes contact with a liner that is attached to the interior portion of the metal acetabulum cup (socket). The acetabulum cup is comprised of titanium metal. Either a plastic, ceramic, or cobalt-chromium metal liner is then placed on the inside of the acetabulum cup. The metal femoral head rotates within the plastic, ceramic, or metal liner, depending on which liner the surgeon selects based on the patient's needs. The cobalt-chromium metal liner is branded by Defendants as the "Ultamet." The Pinnacle Device with an Ultamet liner is a "metal-on-metal" device due to the fact that both articulating surfaces,

the femoral head (ball) and acetabulum liner (socket), are comprised of cobalt-chromium metal.

C. Defendants Did Not Seek Premarket Approval From The FDA, And The FDA Therefore Made No Finding That The Pinnacle Device Is Safe Or Effective

24. The Pinnacle Device is a Class III medical device. Class III devices are those that operate to sustain human life, are of substantial importance in preventing impairment of human health, or pose potentially unreasonable risks to patients.

25. The Medical Device Amendments to the Food, Drug, and Cosmetics Act of 1938 ("MDA"), in theory, require Class III medical devices, including the Pinnacle Device, to undergo premarket approval by the FDA before marketing and distribution, a process which obligates the manufacturer to design and implement a clinical investigation and to submit the results of that investigation to the FDA.

26. Premarket approval is a rigorous process that requires a manufacturer to submit what is typically a multivolume application that includes, among other things, full reports of all studies and investigations of the device's safety and effectiveness that have been published or should reasonably be known to the applicant; a full statement of the device's components, ingredients, and properties and of the principle or principles of operation; a full description of the methods used in, and the facilities and controls used for, the manufacture, processing, and, when relevant, packing and installation of, such device; samples or device components required by the FDA; and a specimen of the proposed labeling.

27. The FDA may grant premarket approval only if it finds that these is reasonable assurance that the medical device is safe and effective and must weigh any probable benefit to health from the use of the device against any probable risk of injury or illness from such use.

28. A medical device on the market prior to the effective date of the MDA (a so-called "grandfathered" device) was not required to undergo premarket approval. In addition, a medical device marketed after the MDA's effective date may bypass the rigorous premarket approval process if the device is "substantially equivalent" to a "grandfathered" pre-MDA device (i.e., a device approved prior to May 28, 1976). This exception to premarket approval is known as the "510(k)" process and simply requires the manufacturer to notify the FDA under section 510(k) of the MDA of its intent to market a device at least 90 days prior to the device's introduction on the market, and to explain the device's substantial equivalence to a pre-MDA predicate device. The FDA may then approve the new device for sale in the United States.

29. Rather than being approved for use by the FDA pursuant to the rigorous premarket approval process, the Pinnacle Device metal-on-metal total hip replacement system was certified to be sold on the basis of Defendants' claim that, under section 510(k) of the MDA, it was "substantially equivalent" to another older metal-on-metal hip implant device that Defendants sold and implanted prior to the enactment of the MDA in 1976.

30. As such, under the 510(k) process, Defendants were able to market the Pinnacle Device with virtually no clinical or non-clinical trials or FDA review of the implant for safety and effectiveness.

31. Because the Pinnacle Device did not go through the extensive premarket approval process but instead was approved through the section 510(k) process, none of the Plaintiff claims against the Defendants in this case are preempted by federal law.

D. Defendants Took No Steps To Test The Pinnacle Device Or They Would Have Discovered That It Leads To Metallosis And Other Complications Before Releasing It On The Market

32. Had Defendants conducted clinical trials of the Pinnacle Device before it was first released on the market in the early 2000's, they would have discovered at that time what they ultimately learned in and around 2007: that the Pinnacle Device results in a high percentage of patients developing metallosis, biologic toxicity and an early and high failure rate due to the release of metal particles in the patient's surrounding tissue when the cobalt-chromium metal formal head rotates within the cobalt-chromium metal acetabular liner.

33. In other words, implantation of the Pinnacle Device results in the nearly immediate systemic release of high levels of toxic metal cobalt-chromium ions into every hip implant patient's tissue and bloodstream. This is because cobalt-chromium metal particles are released by friction from the metal femoral head rotating within the metal liner. The particles then accumulate in the patient's tissue surrounding the implant giving rise to metallosis, pseudotumors, and/or other conditions.

34. The formation of metallosis, pseudotumors, and infection and inflammation causes severe pain and discomfort, death of surrounding tissue and bone loss, and a lack of mobility.

35. The problems with the Pinnacle Device are similar to the issues that gave rise to Defendants' recall of its ASR XL Acetabular System and ASR Hip Resurfacing System.

Like the Pinnacle Device, the ASR is also prone to early failure, and causes metallosis and cobalt toxicity resulting in serious health problems and the need for subsequent revision surgery. As a result, on August 24, 2010, Defendants, in acknowledging the high failure rate of the ASR, recalled more than 93,000 ASRs worldwide.

36. On information and belief, to date, the FDA has received more than l,300 adverse reports regarding problems associated with or attributed to the Pinnacle Device.

37. On information and belief, many recipients of the Pinnacle Device are suffering from elevated levels of chromium and cobalt. On further information and belief, that Defendants are aware that certain recipients of the Pinnacle Device have significantly elevated levels of chromium and cobalt in amounts many times higher than acceptable or recommended safety levels. Notably, the ASR and the Pinnacle Device were designed by the same orthopaedic surgeon, Dr. Thomas Schmalzried.

38. A number of governmental regulatory agencies have recognized the problems that are caused by metal-on-metal implants such as the ASR and Pinnacle Device. For instance, The Medicines and Healthcare Products Regulatory Agency ("MHRA") in Britain investigated Defendants' metal-on-metal total hip replacement system after receiving widespread reports of soft tissue reactions and tumor growth in thousands of patients who had received these implants. MHRA has required physicians to establish a system to closely monitor patients known to have metal-on-metal hips by monitoring the cobalt and chromium ion levels in their blood and to evaluate them for related soft tissue reactions.

39. Similarly, the Alaska Department of Health has issued a bulletin warning of the toxicity of Defendants' metal-on-metal total hip replacement systems. The State of

Alaska, like the MHRA, identified the need for close medical monitoring, surveillance and treatment of all patients who had received these and similar metal-on-metal implants.

40. Despite the public knowledge to the contrary, Defendants continue to misrepresent the Pinnacle Device as a high-quality, safe and effective hip replacement product in their marketing and promotional materials. This is despite the fact that Defendants have known for years that the Pinnacle Device poses a danger to patients that have it implanted.

41. As a result, Defendants continued to sell the Pinnacle Device to doctors who implant them in countless numbers of patients with an unreasonably high percentage of those patients being forced to endure serious injury from metallosis, pseudotumors, and biologic toxicity, among other complications. These patients are reporting severe pain and discomfort and the need for one or more complicated revision surgeries resulting in life-long health problems caused by the defective device.

42. It was not until May 2013 that Defendants announced that they will discontinue their Ultamet Metal-on-Metal Articulation systems worldwide at the end of August of this year.

E. Plaintiff Was Implanted With A Pinnacle Device And As A Result Has Suffered Severe Injuries

43. On or about June 5, 2008, Plaintiff George J. Poniewaz underwent a right total hip arthroplasty procedure at Waukesha Memorial Hospital in Waukesha, Wisconsin. A Pinnacle Device with an Ultamet liner was implanted in place of his right hip.

44. On or about June 25, 2010, Plaintiff underwent a left total hip arthroplasty procedure at Waukesha Memorial Hospital in Waukesha, Wisconsin. A Pinnacle Device with an Ultamet liner was implanted in place of his left hip.

45. After the surgery, friction and wear between the cobalt-chromium metal head and cobalt-chromium metal liner caused large amounts of toxic cobalt-chromium metal ions and particles to be released into Plaintiff's blood and tissue and bone surrounding the implant.

46. As a result, Plaintiff George J. Poniewaz has suffered the following personal and economic injuries as a result of the implantation with the Pinnacle Device: past and future pain, suffering, disability and loss of enjoyment of life; past and future medical expenses; past and future wage loss and impairment of earning capacity; and other compensable injuries and damages.

47. All of the injuries and complications suffered by Plaintiff were caused by the defective design, warnings, construction and unreasonably dangerous character of the Pinnacle Device that was implanted in him. Had Defendants not concealed the known defects, the early failure rate, the known complications and the unreasonable risks associated with the use of the Pinnacle Device, Plaintiff would not have consented to the Pinnacle Device being used in his total hip arthroplasty.

48. The Plaintiff, George J. Poniewaz could not have known that the injuries he suffered were as a result of a defect in the Pinnacle Device until after August 24, 2010 at the earliest, when Defendants recalled their similar ASR model for similar reasons.

49. Plaintiff was unaware of any causal link between the injuries he has suffered and any wrongdoing on the part of Defendants due to the faulty and defective nature of the Pinnacle Device, due in part to the failures of Defendants to properly warn him and his orthopedic physician about the Pinnacle Device's defective and faulty nature. Plaintiff was unable to make an earlier discovery of said causal link despite reasonable diligence because of Defendants' failure to properly warn him and his orthopedic physician about the Pinnacle Device's defective and faulty nature, and their failure to issue any recall or take any other proactive action to date with respect to the injuries being caused to patients that have been implanted with a Pinnacle Device.

CAUSES OF ACTION
FIRST CAUSE OF ACTION NEGLIGENCE
(Against All Defendants)

50. Plaintiff incorporates by reference, as fully set forth therein, each and every allegation set forth in the preceding paragraphs and further allege as follows:

51. Defendants had a duty to exercise reasonable care in the designing, researching, manufacturing, marketing, supplying, promoting, sale, testing, quality assurance, quality control, and/or distribution of the Pinnacle Device into the stream of commerce, including a duty to assure that the device would not cause those who had it surgically implanted to suffer adverse harmful effects from it.

52. Defendants failed to exercise reasonable care in the designing, researching, manufacturing, marketing, supplying, promoting, sale, testing, quality assurance, quality control, and/or distribution of the Pinnacle Device into interstate commerce in that Defendants knew or should have known that those individuals that had the device surgically

implanted were at risk for suffering harmful effects from it including but not limited to partial or complete loss of mobility, loss of range of motion, as well as other severe and personal injuries which are permanent and lasting in nature, physical pain and mental anguish, including diminished enjoyment of life, as well as the need for a revision surgery to replace the device with the attendant risks of complications and death from such further surgery.

53. The negligence of Defendants, their agents, servants, and/or employees, included but was not limited to the following acts and/or omissions:

a. Negligently designing the Pinnacle Device in a manner which was dangerous to those individuals who had the device surgically implanted;

b. Designing, manufacturing, producing, creating, and/or promoting the Pinnacle Device without adequately, sufficiently, or thoroughly testing it;

c. Not conducting sufficient testing programs to determine whether or not the aforesaid Pinnacle Device was safe for use;

d. Defendants herein knew or should have known that Pinnacle Device was unsafe and unfit for use by reason of the dangers to its users;

e. Selling the Pinnacle Device without making proper and sufficient tests to determine the dangers to its users;

f. Negligently tailing to adequately and correctly warn Plaintiff or his orthopedic physician, hospitals and/or healthcare providers of the dangers of Pinnacle Device;

g. Negligently failing to recall their dangerous and defective Pinnacle Device at the earliest date that it became known that the device was, in fact, dangerous and defective;

h. Failing to provide adequate instructions regarding safety precautions to be observed by surgeons who would reasonably and foreseeably come into contact with, and more particularly, implant the Pinnacle Device into their patients;

i. Negligently advertising and recommending the use of the Pinnacle Device despite the fact that Defendants knew or should have known of its dangerous propensities;

j. Negligently representing that the Pinnacle Device offered was safe for use for its intended purpose, when, in fact, it was unsafe;

k. Negligently manufacturing the Pinnacle Device in a manner which was dangerous to those individuals who had it implanted;

l. Negligently producing the Pinnacle Device in a manner which was dangerous to those individuals who had it implanted;

m. Negligently assembling the Pinnacle Device in a manner which was dangerous to those individuals who had it implanted;

n. Defendants under-reported, underestimated and downplayed the serious danger of the Pinnacle Device.

54. Defendants were negligent in the designing, researching, supplying, manufacturing, promoting, packaging, distributing, testing, advertising, warning, marketing and sale of the Pinnacle Device in that they:

a. Failed to use due care in designing and manufacturing the Pinnacle Device so as to avoid the aforementioned risks to individuals that had the devices surgically implanted;

b. Failed to accompany their product with proper warnings;

c. Failed to accompany their product with proper instructions for use;

d. Failed to conduct adequate testing, including pre-clinical and clinical testing and post-marketing surveillance to determine the safety of the Pinnacle Device; and

e. Were otherwise careless and/or negligent.

55. Despite the fact that Defendants knew or should have known that the Pinnacle Device caused harm to individuals that had the device surgically implanted, Defendants continued to market, manufacture, distribute and/or sell the Pinnacle Device.

56. Defendants knew or should have known that consumers such as Plaintiff would suffer foreseeable injury, and/or be at increased risk of suffering injury as a result of Defendants' failure to exercise ordinary care, as set forth above.

57. Defendants' negligence was the proximate cause of Plaintiff George J. Poniewaz's physical, mental and emotional injuries and harm, and economic loss, including past and future medical expenses, which he has suffered and/or will continue to suffer.

58. By reason of the foregoing, Plaintiff George J. Poniewaz experienced and/or will experience severe harmful effects including but not limited to partial or complete loss of mobility, loss of range of motion, as well as other severe and personal injuries which are permanent and lasting in nature, physical pain and mental anguish, including diminished enjoyment of life, as well as the need for a revision surgery to replace the device with the attendant risks of complications and death from such further surgery.

59. Further, as a result of the foregoing acts and omissions, Plaintiff George J. Poniewaz suffered a loss of wages and may in the future suffer a diminished capacity to earn wages.

SECOND CAUSE OF ACTION
STRICT PRODUCTS LIABILITY (MANUFACTURING DEFECT)
(Against All Defendants)

60. Plaintiffs incorporate by reference, as if fully set forth herein, each and every allegation set forth in the preceding paragraphs and further allege as follows:

61. Defendants designed, manufactured, tested, marketed and distributed into the stream of commerce the Pinnacle Device.

62. The Pinnacle Device that was surgically implanted in Plaintiff was defective in its manufacture when it left the hands of Defendants in that it deviated from its intended design and product specifications, rendering the product unreasonably dangerous to patients such as the Plaintiff, in that it posed a serious risk that it could fail early in patients, therefore giving rise to physical injury, pain and suffering, debilitation, and the need for a potential revision surgery to replace the device with the attendant risks of complications and death from such further surgery.

63. This defective condition existed at the time the Pinnacle Device left the control of the Defendants.

64. The defective Pinnacle Device reached the Plaintiff George J. Poniewaz who was an intended consumer and recipient of the product, without substantial change in the condition in which it was sold.

65. As a direct and proximate result of Defendants' placement of the defective Pinnacle Device into the stream of commerce, Plaintiff George J. Poniewaz experienced and/or will experience severe harmful effects including but not limited to partial or complete loss of mobility, loss of range of motion, as well as other severe and personal injuries which are permanent and lasting in nature, physical pain and mental anguish, including diminished enjoyment of life, as well as the potential need for a revision surgery to replace the device with the attendant risks of complications and death from such further surgery.

66. Further, as a result of the foregoing acts and omissions, Plaintiff George J. Poniewaz suffered a loss of wages and may in the future suffer a diminished capacity to earn wages.

THIRD CAUSE OF ACTION
STRICT PRODUCTS LIABILITY (DESIGN DEFECT)
(Against All Defendants)

67. Plaintiffs incorporate by reference, as if fully set forth herein, each and every allegation set forth in the preceding paragraphs and further allege as follows:

68. At all times herein mentioned, Defendants designed, researched, manufactured, tested, advertised, promoted, marketed, sold, and/or distributed the Pinnacle Device as hereinabove described that was surgically implanted in Plaintiff.

69. At all times herein mentioned, the Pinnacle Device designed, researched, manufactured, tested, advertised, promoted, marketed, sold and/or distributed by Defendants was in an unsafe, defective, and inherently dangerous condition, which was dangerous to users such as Plaintiff that had the device surgically implanted.

70. At all times herein mentioned, the Pinnacle Device designed, researched, manufactured, tested, advertised, promoted, marketed, sold and/or distributed by Defendants was in an unsafe, defective, and inherently dangerous condition at the time it left Defendants' possession.

71. The foreseeable risks of harm posed by the Pinnacle Device could have been reduced or avoided by the adoption of a reasonable alternative design by Defendants, including, but not limited to, one in which the metal femoral head was not married with a metal acetabular cup liner.

72. At all times herein mentioned, the Pinnacle Device was expected to and did reach the usual consumers, handlers, and persons coming into contact with said product without substantial change in the condition in which it was designed, produced, manufactured, sold, distributed, and marketed by Defendants.

73. At all times herein mentioned, the Pinnacle Device's unsafe, defective, and inherently dangerous condition was a cause of injury to Plaintiff.

74. At all times herein mentioned, the Pinnacle Device failed to perform as safely as an ordinary consumer would expect when used in an intended or reasonably foreseeable manner.

75. Plaintiff injuries resulted from use of the Pinnacle Device that was both intended and reasonably foreseeable by Defendants.

76. At all times herein mentioned, the Pinnacle Device posed a risk of danger inherent in the design which outweighed the benefits of that design.

77. At all times herein mentioned, the Pinnacle Device was defective and unsafe, and Defendants knew or had reason to know that said product was defective and unsafe, especially when used in the form and manner as provided by Defendants.

78. Defendants knew, or should have known, that at all times herein mentioned that the Pinnacle Device was in a defective condition, and was and is inherently dangerous and unsafe.

79. At the time of the implantation of the Pinnacle Device into Plaintiff George J. Poniewaz the aforesaid product was being used for the purposes and in a manner normally intended, namely for use as a hip replacement device.

80. Defendants, with this knowledge, voluntarily designed their Pinnacle Device in a dangerous condition for use by the public and, in particular, Plaintiff.

81. Defendants had a duty to create a product that was not unreasonably dangerous for its normal, intended use.

82. Defendants designed, researched, manufactured, tested, advertised, promoted, marketed, sold and distributed a defective product which, when used in its intended or reasonably foreseeable manner, created an unreasonable risk to the health of consumers and to Plaintiff, in particular, and Defendants are therefore strictly liable for the injuries sustained by Plaintiff.

83. As a direct and proximate result of Defendants' placement of the defective Pinnacle Device into the stream of commerce, Plaintiff George J. Poniewaz experienced and/or will experience severe harmful effects including but not limited to partial or complete loss of mobility, loss of range of motion, as well as other severe and personal injuries which are permanent and lasting in nature, physical pain and mental anguish, including diminished enjoyment of life, as well as the potential need for a revision surgery to replace the device with the attendant risks of complications and death from such further surgery.

84. Further, as a result of the foregoing acts and omissions, Plaintiff George J. Poniewaz suffered a loss of wages and may in the future suffer a diminished capacity to earn wages.

FOURTH CAUSE OF ACTION
STRICT PRODUCTS LIABILITY (INADEQUATE WARNING)
(Against All Defendants)

85. Plaintiffs incorporate by reference, as if fully set forth herein, each and every allegation set forth in the preceding paragraphs and further allege as follows:

86. Defendants designed, manufactured, tested, marketed and distributed into the stream of commerce the Pinnacle Device.

87. The Pinnacle Device placed into the stream of commerce by Defendants was defective due to inadequate warning, because Defendants knew or should have known that the Pinnacle Device could fail early in patients therefore give rise to physical injury, pain and suffering, debilitation, and the need for a revision surgery to replace the device with the attendant risks of complications and death from such further surgery, but failed to give consumers adequate warning of such risks. Further, the Pinnacle Device placed into the stream of commerce by Defendants was surgically implanted in a manner reasonably anticipated by Defendants.

88. The foreseeable risks of harm posed by the Pinnacle Device could have been reduced or avoided by the provision of reasonable instructions or warnings by Defendants, and the omission of the instructions or warnings rendered the Pinnacle Device not reasonably safe.

89. As a direct and proximate result of Defendants' placement of the defective Pinnacle Device into the stream of commerce, Plaintiff George J. Poniewaz experienced and/or will experience severe harmful effects including but not limited to partial or complete loss of mobility, loss of range of motion, as well as other severe and personal

injuries which are permanent and lasting in nature, physical pain and mental anguish, including diminished enjoyment of life, as well as the potential need for a revision surgery to replace the device with the attendant risks of complications and death from such further surgery.

90. Further, as a result of the foregoing acts and omissions, Plaintiff George J. Poniewaz suffered a loss of wages and may in the future suffer a diminished capacity to earn wages.

FIFTH CAUSE OF ACTION
BREACH OF EXPRESS WARRANTY
(Against All Defendants)

91. Plaintiffs incorporate by reference, as if fully set forth herein, each and every allegation set forth in the preceding paragraphs and further allege as follows:

92. Defendants designed, manufactured, tested, marketed and distributed into the stream of commerce the Pinnacle Device.

93. Defendants expressly warranted that the Pinnacle Device was a safe and effective hip replacement system.

94. These express affirmations of fact were made for the purpose of inducing orthopedic physicians, including the Plaintiff's orthopedic surgeon, to select Defendants' Pinnacle Device instead of other available hip implant products manufactured and distributed by Defendants' competitors.

95. In reliance upon these express representations, the Plaintiff George J. Poniewaz in consultation with his orthopedic physician selected the Pinnacle Device for implantation.

96. The Pinnacle Device placed into the stream of commerce by Defendants did not conform to these express representations because they failed early thereby giving rise to unnecessary physical injury, pain and suffering, debilitation, and the potential need for a revision surgery to replace the device with the attendant risks of complications and death from such further surgery.

97. As a direct and proximate result of Defendants' breach of express warranties regarding the safety and effectiveness of the Pinnacle Device, Plaintiff George J. Poniewaz has suffered significant damages, including but not limited to physical injury, economic loss, post and future medical expenses, pain and suffering, and the need for further surgery to replace the faulty device, and will continue to suffer such damages in the future.

SIXTH CAUSE OF ACTION
BREACH OF IMPLIED WARRANTY OF FITNESS FOR A PARTICULAR PURPOSE
(Against All Defendants)

98. Plaintiffs incorporate by reference, as if fully set forth herein, each and every allegation set forth in the preceding paragraphs and further allege as follows:

99. Defendants designed, manufactured, tested, marketed and distributed into the stream of commerce the Pinnacle Device.

100. At the time Defendants designed, manufactured, tested, marketed and distributed into the stream of commerce the Pinnacle Device, Defendants knew the use for which the Pinnacle Device was intended, and impliedly warranted the Pinnacle Device to be of merchantable quality and safe for such use.

101. Plaintiff reasonably relied upon the skill and judgment of Defendants as to whether the Pinnacle Device was of merchantable quality and safe for its intended use.

102. Contrary to Defendants' implied warranties, the Pinnacle Device was not of merchantable quality or safe for its intended use, because the Pinnacle Device was unreasonably dangerous as described above.

103. As a direct and proximate result of Defendants' breach of implied warranties regarding the safety and effectiveness of the Pinnacle Device, Plaintiff George J. Poniewaz has suffered significant damages, including but not limited to physical injury, economic loss, past and future medical expenses, pain and suffering, and the potential need for further surgery to replace the faulty device, and will continue to suffer such damages in the future.

SEVENTH CAUSE OF ACTION
NEGLIGENT MISREPRESENTATION
(Against All Defendants)

104. Plaintiffs incorporate by reference, as if fully set forth herein, each and every allegation set forth in the preceding paragraphs and further allege as follows:

105. The Defendants made false representation of fact to the public, to Plaintiff George J. Poniewaz and to his orthopedic physician regarding the high-quality, safety and effectiveness of the Pinnacle Device. Defendants provided this false information to induce the public, Plaintiff and his orthopedic physician to purchase and implant a Pinnacle Device.

106. The Defendants knew or should have known that the information they supplied regarding the purported high-quality, safety and effectiveness of the implant to induce Plaintiff and his orthopedic physician to purchase and use a Pinnacle Device was false.

107. The Defendants were negligent in obtaining or communicating false information regarding the purported high-quality, safety and effectiveness of the Pinnacle Device.

108. Plaintiff and his orthopedic physician believed these false representations were true and relied on the false information supplied by the Defendants to his detriment by causing the Pinnacle Device to be purchased and implanted in Plaintiff.

109. Plaintiff and his orthopedic physician were justified in their reliance on the false information supplied by the Defendants regarding the purported high-quality, safety and effectiveness of the Pinnacle Device.

110. As a direct and proximate result of Defendants' negligent misrepresentations, Plaintiff George J. Poniewaz has suffered significant damages, including but not limited to permanent physical injury, economic loss, pat and future medical expenses, pain and suffering and the potential need for revision surgery to repair the physical damage to Plaintiff caused by the Pinnacle Device.

EIGHTH CAUSE OF ACTION
FRAUD
(Against All Defendants)

111. Plaintiffs incorporate by reference, as if fully set forth herein, each and every allegation set forth in the preceding paragraphs and further allege as follows:

112. Defendants made representations to Plaintiff George J. Poniewaz and his orthopedic physician that their Pinnacle Device is a high-quality, safe and effective hip replacement system.

113. Before they marketed the Pinnacle Device that was implanted in Plaintiff, Defendants knew or should have known of the unreasonable dangers and serious health risks that such a metal-on-metal total hip replacement system posed to patients like Plaintiff.

114. As specifically described in detail above, Defendants knew that the Pinnacle Device subjected patients to early failure, painful and harmful physical reactions to toxic metallic particles and ions, death of tissue, bone loss and the need for explants and revision surgery.

115. Defendants' representations to Plaintiff and his orthopedic physician that their Pinnacle Device is high-quality, safe and effective were false, and were made with the intent to deceive the plaintiff and his orthopedic physicians in order to induce them to select Defendants' Pinnacle Device instead of other available hip implant products manufactured and distributed by Defendants' competitors.

116. Defendants concealed their knowledge of the unreasonable risks and dangers associated with the use of the Pinnacle Device to induce Plaintiff and many thousands of others to purchase the system for surgical implantation in their bodies.

117. Neither Plaintiff nor his orthopedic physician knew of the falsity of Defendants' statements regarding the Pinnacle Device.

118. Plaintiff and his orthopedic physician relied upon and accepted as truthful Defendants' representations regarding the Pinnacle Device.

119. Plaintiff and his orthopedic physician had a right to rely on Defendants' representations and in fact did rely upon such representations. Had Plaintiff known that the Pinnacle Device would fail early and expose his to the unreasonable risk of toxic metals,

metallosis, and multiple revision surgeries he would not have purchased or allowed the Pinnacle Device to have been surgically implanted in his.

120. As a direct and proximate result of Defendants' fraudulent representations, Plaintiff George J. Poniewaz has suffered significant damages, including but not limited to permanent physical injury, economic loss, past and future medical expenses, pain and suffering and the potential need for additional surgeries to repair the physical damage caused to him by the Pinnacle Device.

NINTH CAUSE OF ACTION
LOSS OF CONSORTIUM
(Against All Defendants)

121. Plaintiffs incorporate by reference, as if fully set forth herein, each and every allegation set forth in the preceding paragraphs and further allege as follows:

122. Plaintiff Jill Poniewaz is and at all times relevant hereto has been the lawful spouse of Plaintiff George J. Poniewaz and as such Plaintiff Jill Poniewaz is entitled to the comfort and enjoyment of his society and services.

123. As a direct and proximate result of the foregoing misconduct of the Defendants, Jill Poniewaz has been deprived of her spouse's companionship, services, solace, consortium, affection and attention to which he is entitled.

124. As a result of all of the foregoing, Plaintiff Jill Poniewaz has been and will continue to be injured and damaged.

TENTH CAUSE OF ACTION
PUNATIVE DAMAGES
(Against All Defendants)

125. Plaintiffs incorporate by reference, as if fully set forth herein, each and every allegation set forth in the preceding paragraphs and further allege as follows:

126. In engaging in the forgoing acts and omissions, Defendants acted in an intentional disregard of plaintiff's rights, so as to justify an award of punitive damages.

PRAYER FOR RELIEF

WHISEFORE, Plaintiffs pray for the following relief:

A. Judgment in favor of Plaintiffs and against all Defendants, for damages in such amounts as may be proven at trial;

B. Compensation for both economic and non-economic losses, including but not limited to medical expenses, loss of earnings, disfigurement, pain and suffering, mental anguish and emotional distress, in such amounts as may be proven at trial;

C. Punitive and/or exemplary damages in such amounts as may be proven at trial;

D. Attorneys' fees and costs;

E. Pre- and post-judgment interest; and

F. Any and all further relief, both legal and equitable, that the Court may deem just and proper.

Respectfully submitted,

Date: August 6, 2013

/s/ Edward E. Robinson
Edward E. Robinson
Attorney Bar No. 01025122
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JURY DEMAND

Plaintiffs George J. Poniewaz and Jill Poniewaz hereby demand a trial by jury.

Date: August 6, 2013

/s/ Edward E. Robinson
Edward E. Robinson